UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
McALLEN DIVISION

ROY ECKHARDT and YOLANDA C. ECKHART, Plaintiffs, v. QUALITEST PHARMACEUTICALS, INC.; WYETH, INC., individually and as successor-in-interest to A.H. ROBBINS COMPANY, INC. and AMERICAN HOME PRODUCTS; SCHWARZ PHARMA, INC.; and VINTAGE PHARMACEUTICALS, LLC; Defendants.	§ § § § § § § § § § § § § § §	CASE NO. 7:11-cv-00235

PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO ALTER OR AMEND JUDGMENT

I. INTRODUCTION

On April 30, 2012, this Court issued a Order in which it granted a Motion to Dismiss filed by Defendants Qualitest Pharmaceuticals, Inc. and Vintage Pharmaceuticals, LLC (collectively "Generic Defendants"). [Doc. 75]. Thereafter on August 9, 2012, the Court issued a Memorandum Opinion granting Defendants Wyeth, Inc. and Schwarz Pharma, Inc.'s (collectively "Brand Defendants"). On August 14, 2012, the Court entered final judgment in favor of Defendants on all of Plaintiffs' claims. [Doc. 80]. In its ruling, the Court repeatedly noted that there was no dispute that Defendants had provided warnings and information to Plaintiff's prescribing physicians. For the reasons set forth below, Plaintiffs respectfully request

that the Court reconsider its previous rulings dismissing their claims, and allow this case to proceed to trial.

II. LAW AND ARGUMENT

A. Standard of Law

A motion brought pursuant to Rule 59, is not controlled by the same exacting substantive requirements as Fed. R. Civ. P. 60(b). *Lavespere v. Niagara Machine & Tool Works, Inc.,* 910 F.2d 167, 173–74 (5th Cir.1990), *abrogated on other grounds by Little v. Liquid Air Corp.,* 37 F.3d 1069 (5th Cir.1994). "Unlike Rule 60(b), Rule 59(e) does not set forth any specific grounds for relief." *Id.* Relief under Rule 59 is appropriate (1) where there has been an intervening change in the controlling law; (2) where the movant presents newly discovered evidence; or (3) to correct a manifest error of law or fact. *Schiller v. Physicians Res. Grp. Inc.,* 342 F.3d 563, 567 (5th Cir. 2003); *see also Rosenblatt v. United Way of Greater Houston,* 607 F.3d 413, 419 (5th Cir. 2010).

In exercising its discretion under Rule 59(e), the court "must strike the proper balance between two competing imperatives: (1) finality, and (2) the need to render just decisions on the basis of all the facts." *Edward H. Bohlin Co., Inc. v. Banning Co., Inc.,* 6 F.3d 350, 355 (5th Cir. 1993). In balancing these interests, courts may consider many different factors, although no one in particular is determinative. *Ford v. Elsbury,* 32 F.3d 931, 937–38 (5th Cir.1994); *see also Texas A & M Research Foundation v. Magna Transp., Inc.,* 338 F.3d 394 (5th Cir. 2003). Unlike a motion brought pursuant to Rule 60, which requires a specific showing regarding the prior unavailability of evidence, Rule 59 requires no special showing in this regard. *Ford,* 32 F.3d at 937.

B. Order Granting Generic Defendants' Motion to Dismiss

In its Order Granting Generic Defendants Motion to Dismiss, the Court acknowledges that the preemption announced by the Supreme Court's *Mensing* decision applies to claims arising under "state laws requiring generic drugs to have different labels than the FDA-approved brand-name labels." [Doc. 75], pg. 6. Despite the fact that Plaintiffs' Second Amended Complaint asserted numerous theories of liability, the Court determined that "this is essentially a products liability case, with the claim arising from a failure to warn." *Id.* While the issue was not raised in the parties' briefing, the Court began its analysis by finding that the Fifth Circuit's decision in *Lofton v. McNeil Consumer and Specialty Pharmaceuticals*, precluded all of Plaintiff's failure to warn claims, "to the extent that Generics only provided labeling and information that was approved by the FDA." [Doc. 75], pg. 9. The court also found that Plaintiffs' assertion that Generic Defendants could be held liable for failing to perform post-marketing surveillance and reporting on its metoclopramide products – in violation of federal law – could not proceed, because Plaintiffs would be unable to prove causation. *Id.*

The Court then analyzed the other non-warning causes of action appearing in Plaintiffs' Complaint. With regard to the assertion made in Plaintiffs' Response to Generic Defendants' Motion that "Generic Defendants never provided Plaintiff or his physicians with ANY warning or other information with regard to metoclopramide," the Court found that such an assertion was "directly contradicted" by allegations appearing within Plaintiffs' Second Amended Complaint. *Id.* at pg. 10. With respect to the arguments in Plaintiffs' Response that Generic Defendants could be held liable for failing to update and communicate a warning added to the FDA-approved label in 2004 which indicated that "[t]herapy with metoclopramide should not exceed 12 weeks in duration," the Court found that these claims were not supported by the allegations appearing in the operative Complaint, and therefore declined to consider the argument entirely.

Id. at pg. 11. The Court also recharacterized the argument appearing in Plaintiffs' Response asserting that "the laws of Texas do not *require* that a manufacturer change the content of its warning, but rather *prohibit* a manufacturer from selling a dangerous product" to assert that Generic Defendants "should have withdrawn metoclopramide from the market." *Id.* The Court, while stating its doubt that such a claim even appeared within Plaintiffs' Complaint, found that such a claim would impermissibly conflict with federal law, and was therefore preempted. *Id.* at pg. 12. The Court also found that Plaintiffs' design defect claims were precluded because Generic Defendants "were obligated to use a certain design." *Id.* The Court also dismissed Plaintiffs' claims brought pursuant to the Deceptive Trade Practices – Consumer Protection Act ("DTPA") in reliance on the justification cited for dismissal of Plaintiff's other claims. *Id.* at 14. The Court did not address the breach of warranty claims appearing in Plaintiffs' complaint.

1. *Lofton* Does Not Preclude Plaintiffs' Failure to Warn Claims

As stated above, the Court found that the decision of the Fifth Circuit in *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012) mandates that Plaintiffs' failure to warn claims in the present case be dismissed. The Fifth Circuit issued the *Lofton* decision on February 22, 2012, after briefing on Generic Defendants' Motion had been submitted to the Court. As a result, neither party addressed the *Lofton* decision in their briefing to this Court. Still, the Court *sua sponte* determined that *Lofton* controlled the outcome of this case because Plaintiffs had "specifically den[ied] the applicability of the presumption [the Generic Defendants were not liable] by alleging that Generics withheld information from the FDA and misrepresented information to the FDA." [Doc. 75], pg. 8. The *Lofton* Court had determined that claims which required a plaintiff to rebut a presumption of non-liability by showing that Defendants had withheld information from the FDA were preempted by the operation of federal

law. *See Lofton*, 672 F.3d at 381 ("Because we conclude that § 82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*, we hold that it is preempted by the FDCA unless the FDCA itself finds fraud").

The Court's Order ignored, however, that § 82.007(b)(1) is not the only manner by which Plaintiffs could rebut the presumption of non-liability, nor did it consider the fact that the allegations of Plaintiffs' Second Amended Complaint successfully rebut the presumption by other means. Specifically, Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(3) provides that a claimant may rebut the presumption of non-liability by establishing that:

> (A) the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration;
> (B) the product was used as recommended, promoted, or advertised; and
> (C) the claimant's injury was causally related to the recommended, promoted, or advertised use of the product.

Consistent with § 82.007(b)(3), Plaintiffs' Second Amended Complaint contains the following allegations:

- Defendants jointly and severally marketed, manufactured and distributed Reglan/metoclopramide and ***encouraged the long-term use of these drugs***, misrepresented the effectiveness of these drugs and concealed the drug's dangerous side effects.

- Reglan/metoclopramide is indicated only as short-term therapy for symptomatic gastroesophageal reflux and acute and recurrent diabetic gastric stasis.

- Reglan/metoclopramide is indicated only for use no greater than 12 weeks; however, Defendants represented that Reglan/metoclopramide was safe for use to treat nausea and/or esophageal reflux for durations that exceed 12 weeks.

Plaintiffs' Second Amended Complaint, [Doc. 22], ¶¶ 3.56-3.58.

As a result, Plaintiffs' the viability of Plaintiffs' claims do not depend on the availability of § 82.007(b)(1). They have also rebutted the presumption under §82.007(b)(3), which was not addressed by the Fifth Circuit in its *Lofton* Decision. Furthermore, the *Lofton* decision itself

acknowledges that certain claims "that parallel or reinforce the [FDA's] efforts" are not subject to preemption, as provided for by Supreme Court precedent. *Lofton*, 672 F.3d at 377. As shown below, Plaintiffs have asserted such claims against Generic Defendants.

2. Generic Defendants' "Parallel Claims" Are Actionable

In *Bass v. Stryker Corp.*, the U.S. Fifth Circuit Court of Appeals reaffirmed its holding in *Hughes v. Boston Scientific Corp.* that failure to comply with FDA requirements, such as post-marketing reporting requirements, may subject a manufacturer to liability under Texas law.

In *Hughes*, the Court found that claims that a manufacturer failed to provide reports of injuries associated with its products to the FDA were not preempted, and could proceed under Mississippi law. *Hughes v. Boston Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011). While finding that claims which attempted to impose liability on the manufacturer despite the manufacturer's compliance with federal law would be preempted, the court found claims premised on a violation FDA regulations would not be:

> Rather, a failure to warn claim limited to an assertion that the defendant violated a relevant federal statute or regulation is "parallel" to federal requirements as defined in *Riegel*, in which the Court stated that "§ 360k does not prevent a State from providing a damages remedy for claims premised on violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." 552 U.S. at 330, 128 S.Ct. 999 (quoting *Medtronic*, 518 U.S. at 495, 513, 116 S.Ct. 2240 (O'Connor, J., concurring in part and dissenting in part)).

The court rejected the notion appearing in the Court's Order that if Generic Defendants had fulfilled their post-marketing safety surveillance and reporting obligations, "that knowledge would only be helpful to the extent it was communicated through labeling." [Doc. 75], pg. 9. Instead, the court noted that the information supplied to the FDA by the defendants was disseminated to the public, so that it could be relied upon by physicians and researchers:

> The summary judgment evidence indicates that manufacturers provide these reports to the FDA, the FDA then disseminates the reports to the public, and the reports are then

> relied upon by physicians and authors of medical journals in comparing the relative safety of medical devices.

Id. at 771, n.5. As stated by the Court, "[a] factfinder could infer that a manufacturer's failure to provide this information as required by FDA regulations is a parallel violation of the state duty to provide reasonable and adequate information about a device's risks." *Id.* at 770-71.

In *Bass,* decided after *Mensing,* the 5th Circuit reversed the Northern District of Texas' dismissal of Plaintiff's negligence, strict liability, breach of implied warranty claims along with claims brought under the Deceptive Trade Practices Act against a medical device manufacturer to the extent these claims were premised on a violation of duties imposed by federal law. 669 F.3d 501 (2012). The Court clarified the type of claim which would be allowed to proceed:

> To illustrate, suppose a manufacturer had represented to the FDA in its pre-approval documentation that each hip implant component would be sterilized for ten minutes at 800 degrees. We would accept a parallel claim that pleaded that the manufacturer instead sterilized the component at only 200 degrees for five minutes, as that would "violate" what it told the FDA. However, if the plaintiff's claim was that proper sterilization required twenty minutes at 1000 degrees or some other method of sterilization altogether, this claim would not be allowed, as it would "add to" the regulatory requirements.

Bass v. Stryker Corp., 669 F.3d 501, 512-13 (5th Cir. 2012). Thus, under *Hughes* and *Bass,* if a Plaintiff may prove her state law claim by showing that the actions of the Defendant for which they are to be held liable were in violation of provisions of the FDCA or FDA regulations, such a claim would not be preempted.

In addition, both the *Hughes* and *Stryker* Courts rejected the argument that allowing a Plaintiff to premise a state law claim on violations of federal provisions was not an attempt to assert a private right of action under the FDCA:

> Hughes's claim is not analogous to the "fraud-on-the-FDA" theory in *Buckman.* The plaintiffs in *Buckman* were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations; the plaintiffs did not assert violation of a state tort duty. In contrast, Hughes is asserting a Mississippi tort claim based on the underlying state duty to warn about the dangers or risks of product. She seeks to prove Boston Scientific's breach of the state duty by showing that Boston Scientific violated the

> FDA's MDR regulations. Because Hughes is asserting a recognized state tort claim, her claim is comparable to the tort claims in *Silkwood* and *Lohr* that *Buckman* recognized as surviving implied preemption. The Seventh Circuit reached a similar conclusion, holding that the plaintiff's negligence claims based on the manufacturer's violation of the FDA's specifications were not impliedly preempted under *Buckman* because the plaintiffs were asserting breach of a "recognized state-law duty" rather than "an implied right of action under federal law."
>
> Notably, Hughes's claim does not depend on speculation that the FDA would have taken any particular regulatory action in response to violation of the regulations at issue, as in *Buckman.* Moreover, Boston Scientific's interpretation of *Buckman* barring this otherwise parallel state claim is inconsistent with the Supreme Court's reasoning in *Riegel,* decided long after *Buckman. Riegel* unequivocally held that parallel state claims survive a defendant's preemption defense under the MDA because states may impose an additional "damages remedy for claims premised on violation of FDA regulations." *Riegel,* 552 U.S. at 330, 128 S.Ct. 999. Our conclusion in this respect is also supported by our decision in *Gomez,* decided years after *Buckman,* in which we permitted a negligence claim for defective manufacturing to proceed. Thus, we hold that Hughes's failure to warn claim is not impliedly preempted.

Id. at 775-76.

The *Stryker* Court determined that the above finding of the *Hughes* Court was likewise applicable to claims brought pursuant to Texas law:

> Stryker argues that *Hughes* is distinguishable because it is based on Mississippi law, which could allow a plaintiff to show that a defendant violated its duty of care by proving a federal regulatory violation. Stryker asserts that under Texas law, "statutory and regulatory violations do not establish a violation of the state standard of care unless negligence per se applies." It contends that even if Bass pleaded negligence per se, Texas would not permit a showing of negligence per se based on FDCA violations.
>
> We reject Stryker's attempt to distinguish *Hughes* on this basis; even if Stryker is correct that Bass may not rely on the theory of negligence per se, he may still have a negligence cause of action. Indeed, as noted by the Texas Supreme Court, "[n]egligence per se is a tort concept whereby a legislatively imposed standard of conduct is adopted by the civil courts as defining the conduct of a reasonably prudent person." "In such a case the jury is not asked to judge whether or not the defendant acted as a reasonably prudent person would have acted under the same or similar circumstances; the statute itself states what a reasonably prudent person would have done." Even though Bass may not be able to rely on the theory of negligence per se to establish a violation of the standard of care, Bass has sufficiently alleged facts, which, if true, would support a claim that Stryker was negligent.

> Indeed, it is evident from the Texas Supreme Court's discussion in *Worthy v. Collagen Corp.*, that it would not disallow tort claims predicated on violations of FDA regulations. *Purcel* also indicated that 21 U.S.C. § 337(a) did not preempt negligence and products liability causes of action under Texas law. Yet another court concluded that "claims based on a manufacturer's failure to follow the FDA's regulations and procedures in manufacturing and marketing a device are not preempted." We therefore conclude that Bass's parallel state claims are not preempted by 21 U.S.C. § 337(a).

Bass, 669 F.3d at 514; citing *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex.1979); *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex.1998); *Purcel v. Adv. Bionics Corp.*, 3:07-CV-1777-M, 2010 WL 2679988 (N.D. Tex. 2010); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 138 (Tex.App.—Houston [1st Dist.] 2005, pet. denied).

3. The Court Should Have Considered Plaintiffs' Arguments Regarding the 2004 Label Change

As stated above, the Court in this case declined to consider the arguments appearing in Plaintiffs' Response which were directed at the Generic Defendants' failure to incorporate and communicate warnings added to the metoclopramide label in 2004 which indicated that therapy should not exceed 12 weeks in duration. The Court found that these arguments were "very different" from the claims appearing in Plaintiffs' Second Amended Complaint, and that the claims "focus on alleged failures to update the labeling *to warn of the actual risks associated with metoclopramide."* [Doc. 75], pg. 11 (emphasis in original). The Court also found that allegations in the operative complaint "directly contradict[ed]" the argument appearing in Plaintiffs' response that Generic Defendants never provided Plaintiff or his physician with any information about metoclopramide." [Doc. 75], pp. 10-11. The Court committed error in this regard, as shown below.

First, the allegations appearing in Plaintiffs' Complaint are not inconsistent with the assertion that Generic Defendants did not provide any information to Plaintiff or his physicians. As can clearly be seen from the allegations appearing in the Complaint, Plaintiffs plead that the

Brand Defendants (also referred to as the "Reference Listed Drug" "RLD" or "NDA Holder" disseminated the information relied upon by Plaintiff's physician with prescribing metoclopramide, and that the Generic Defendants adopted these representations for their own products:

- Upon information and belief, in prescribing the Reglan/metoclopramide to Mr. Eckhardt on a long-term basis, his prescribing doctor relied upon information published in the package inserts and/or the Physicians' Desk Reference (hereinafter referred to as "PDR") or otherwise disseminated by the manufacturer of the product, also known as the Reference Listed Drug Company (hereinafter referred to as "RLD") and/or the New Drug Application Holder (hereinafter referred to as "NDA Holder").

- Wyeth intentionally and negligently disseminated misleading information to physicians across the country, through the PDR, about the risks of long-term ingestion of Reglan/metoclopramide and the increased risk of extrapyramidal side effects, including tardive dyskinesia.

- Mr. Eckhardt was not aware of information different from or contrary to the inaccurate, misleading, materially incomplete, false and/or otherwise inadequate information disseminated in the PDR, RLD, or by the NDA Holders.

- Defendants knew or ought to have realized that physicians commonly consult the information disseminated by the name brand manufacturer, in the PDR or otherwise, and rely upon that information in their decisions concerning the prescribing of those products for their patients.

- Defendants knew or should have known, specifically, that physicians would rely upon the information disseminated to them by the brand manufacturer, regardless of whether the prescriptions might be filled with either the name brand product, Reglan, or generic Reglan/metoclopramide, and that many patients, in accordance with those prescriptions, would be likely to ingest Reglan/metoclopramide.

- Defendants Wyeth (and particularly its corporate predecessor in interest, A. H. Robins Company, prior to its merger with and into Wyeth) and Schwarz Pharma disseminated the false information referenced above to physicians and, indirectly, to their patients, knowing the information to be false or in conscious disregard of whether it was false or not false, with the intention to deceive the physicians, and indirectly their patients, and to induce the physicians to prescribe Reglan and/or metoclopramide products.

- Generic drug company defendants Qualitest and Vintage relied upon Wyeth and Schwarz Pharma to communicate to physicians adequate information concerning the appropriate uses and risks entailed in the uses of metoclopramide products,

> including both Reglan and the bioequivalent and therapeutically equivalent generic metoclopramide products, and each impliedly adopted, as applicable to its own generic metoclopramide product, such information as was disseminated about Reglan and/or metoclopramide by defendants Wyeth and Schwarz Pharma.

[Doc. 22], ¶¶ 3.16, 3.26, 3.43, 3.47, 3.85, 4.11; *see also, id.*, at ¶¶ 3.25, 3.84, 4.07, 4.09.

Likewise, the assertion that Generic Defendants failed to communicate the warning added to the FDA-approved labeling for metoclopramide in 2004 is also supported by the allegations in Plaintiffs' Complaint. As the Supreme Court recognized in *Mensing*, "[i]n 2004, the brand-name Reglan manufacturer requested, and the FDA approved, a label change to add that "[t]herapy should not exceed 12 weeks in duration." *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2572 (2011) *reh'g denied*, 132 S. Ct. 55 (U.S. 2011). Despite the fact that after 2004, the metoclopramide label approved by the FDA, and which was required by federal law to appear in the labels for Generic Defendants' metoclopramide products, Plaintiffs alleged the following:

- Defendants knowingly concealed from physicians material facts bearing on the interpretation of package insert disclosures that exposure to Reglan/metoclopramide can lead to tardive dyskinesia and other extrapyramidal side effects, that the risk is "believed" to increase with duration of therapy and total cumulative dose, and that therapy for longer than 12 weeks "cannot be recommended."

- Defendants also concealed the fact that the treatment of chronic or intermittent gastroesophageal reflux and/or diabetic gastroparesis and/or other gastric disorders with Reglan/metoclopramide for longer than 12 weeks is unlikely to be reasonably safe.

- Defendants breached their duty and were negligent in their actions, misrepresentations, and omissions toward Plaintiffs in that Defendants:

  - Failed to adequately warn consumers and medical prescribers (but instead actively encouraged the sale of Reglan/metoclopramide), about the following: (1) that Reglan/metoclopramide should not be prescribed for more than 12 weeks

  - Failed, completely, to warn the Plaintiff of any risks associated with his ingestion of Reglan/metoclopramide

- Defendants made the referenced misrepresentations and actively concealed adverse information at a time when the Defendants knew, or should have known, that Reglan/metoclopramide had defects, dangers, and characteristics that were other than

> what Defendants had represented to Plaintiffs and the health care industry generally. Specifically, Defendants misrepresented to and/or actively concealed from Plaintiffs and the consuming public that: (c.) [p]atients on Reglan/metoclopramide should not take it for more than 12 weeks.

Id. at ¶¶ 3.105, 3.107, 4.03(g), 4.03(j); 4.18(c). Other Courts considering similar allegations have found that there is simply no inconsistency. *See Lyman v. Pfizer, Inc.*, 2:09-CV-262, 2012 WL 2970627 (D. Vt. 2012). As a result, the Court's finding that the arguments presented in Plaintiffs' Response were unsupported by the allegations appearing in Plaintiffs' Complaint, and the finding that the allegations are directly contradictory are in error.

Furthermore, even *if* the allegations in Plaintiffs' Complaint were inconsistent or contradictory, that would not justify the dismissal of their Complaint. The Court's finding that Plaintiffs' claims were subject to dismissal because of contradictory allegations was in error, as it does not consider that the Federal Rules explicitly permit a plaintiff to allege facts or claims that are inconsistent. In particular, Federal Rule of Civil Procedure 8(d) expressly provides:

> (2) ***Alternative Statements of a Claim or Defense.*** A party may set out 2 or more statements of a claim or defense alternatively or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient.
>
> (3) ***Inconsistent Claims or Defenses.*** A party may state as many separate claims or defenses as it has regardless of consistency.

See also, In re King Enterprises, Inc., 678 F.2d 73, 76-77 (8th Cir. 1982); *Molsbergen v. U.S.*, 757 F.2d 1016, 1018-19 (9th Cir. 1985) (collecting cases); *United Technologies Corp. v. Mazer*, 556 F.3d 1260, 1273-74 (11th Cir. 2009) (district court erred in dismissing plaintiff's complaint on basis that allegations were "irreconcilably inconsistent"). The rule permits inconsistency in both legal and factual allegations, even where inconsistencies appear within a single count or allegation. *See Indep. Enterprises Inc. v. Pittsburgh Water and Sewer Auth.*, 103 F.3d 1165, 1175 (3rd Cir. 1997), citing *Babcock & Wilcox Co. v. Parsons Corp.*, 430 F.2d 531, 536 (8th Cir.

1970); *see also Henry v. Daytop Village, Inc.*, 42 F.3d 89, 94-96 (2nd Cir. 1994). Rule 8 also requires that pleadings be construed so as to do justice. Fed R. Civ. P. 8(e).

In addition, under Texas law, the adequacy of a warning is typically an issue to be determined by the finder of fact. *See Centocor, Inc. v. Hamilton*, 10-0223, 2012 WL 2052783 (Tex. 2012), reh'g denied (Aug. 17, 2012). Therefore, whether a particular warning was adequate or inadequate requires a weighing of the particular facts of a situation, and what might constitute an inadequate warning in one situation may be considered adequate (or less inadequate) under others. Other courts considering the same issue have identified the fallacy of the logic employed by the Court and rejected it in cases involving metoclopramide:

> In dismissing Plaintiff's claims because of inconsistent allegations, the Defendants further argue that plaintiffs have already admitted the un-updated labels would have been inadequate even if they included the then-newly-mandated FDA labels. Defendants think this point shows plaintiffs' position is inconsistent with basic tort concepts of duty and causation. This is a misplaced and premature argument. As La. R.S. 9:2800.53(9) and 9:2800.57(C) make clear, defendants' legal duties to warn do not change based on what these two plaintiffs subjectively think adequate because their potential breach of the duty to warn is an objective inquiry into the mind of the ordinary, reasonable user. Moreover, defendants may be mistaking causation with damages in this scenario. In the abstract, a stronger warning, even if still "inadequate" in plaintiffs' mind for purposes of their case against the brand-name manufacturer, could nonetheless be inadequate to a lesser degree, thereby potentially permitting a lower recovery without necessarily obviating causation. Regardless, plaintiffs are permitted to inconsistently plead separate causes of action under Fed. Rule Civ. P. 8(d)(3) without electing their remedy at the pleading stage.

Cooper v. Wyeth, Inc., CIV.A. 09-929-JJB, 2012 WL 733846 (M.D. La. 2012).

4. Generic Defendants Had A Duty To Provide Warnings About Their Drug Products

The Supreme Court of Texas recently confirmed the application of the learned intermediary doctrine to certain claims in the context of prescription drugs. *See Centocor, Inc. v. Hamilton,* --- S.W.3d ----, 2012 WL 2052783 (2012). In its opinion the Court explicitly relied upon *Alm v. Aluminum Co. of Am.,* 717 S.W.2d 588 (Tex. 1986) in outlining the requirements Texas law places on a pharmaceutical manufacturer:

> For reasons stated in *Humble Sand*, *Alm*, and *Gravis*, we hold that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has not further duty to warn the end users directly.

Id. at *14 (internal citations omitted). The Court then specifically cited to *Alm* for the following proposition:

> But as we have previously indicated, when the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient.

Id.

Not only did the *Centocor* opinion validate Plaintiff's reliance on *Alm* as providing the correct principles to be considered in this case, the Court also quoted precisely the portions of the opinion which establish that Generic Defendants had not fulfilled their duties under the learned intermediary doctrine:

> [A] manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of a product. However, the mere presence of an intermediary does not excuse the manufacturer from warning those whom it should reasonably expect to be endangered by the use of its product. The issue in every case is whether the original manufacturer has a reasonable assurance that its warning will reach those endangered by the use of its product.
> …
> Alcoa should be able to satisfy its duty to warn consumers by proving that its intermediary was adequately trained and warned, familiar with the propensities of the product, and capable of passing on a warning. But, if Alcoa failed to adequately warn and train [the intermediary] or if [the intermediary] was incapable of passing on the received warning, Alcoa would not have discharged its duty to the ultimate consumer.

Id. at *12.

Furthermore, it should also be noted that *Centocor* does not support the Court's finding the only claims appearing in Plaintiffs' Complaint are for failure to warn. The *Centocor* decision expressly limited its determination that the claims at issue were "failure-to-warn" claims subject to the learned intermediary doctrine to situations involving fraud by omission. *Centocor*, at *23, n. 30 ("We need not decide whether the learned intermediary doctrine applies against a

prescription drug manufacturer in a common-law fraud or misrepresentation claim based on an overt misrepresentation"). The distinction between failing to provide additional warnings, and actively misrepresenting the side effects was also addressed in Plaintiff's original Response.

Furthermore, while the learned intermediary doctrine may apply to Plaintiff's claims against the Generic Defendants, it does not follow that these claims are therefore preempted under the Supreme Court's decision in *Mensing*. The learned intermediary doctrine is not an affirmative defense. *Id.* at *20; quoting *Ackermann*, 526 F.3d at 207. Rather, under Texas law, the doctrine merely delineates to whom a defendant owes the duty to warn, but is not used to show that the plaintiff has no valid case. *Id.* As a result, the liability of a manufacturer whose products may only be prescribed by a physician may be predicated on a theory that the drug was "unreasonably dangerous" because "under all the circumstances under which it is marketed, it subjected the Plaintiff to an unreasonable risk of harm." *Crocker v. Winthrop Laboratories, Division of Sterling Drug, Inc.*, 514 S.W.2d 429, 431 (Tex. 1974); *In re Norplant Contraceptive Products Liability Litigation*, 955 F.Supp. 700, 709 (E.D. Tex. 1997). As should be clear, Texas law recognizes claims against pharmaceutical manufacturers different from the type of claim considered by the *Mensing* Court. The Court erred in finding that these other claims were subject to dismissal.

5. Plaintiffs' Strict Liability and Design Defect Claims Should Be Allowed to Proceed

In May of this year, the U.S. First Circuit Court of Appeals rejected the Court's finding that design defect claims against generic pharmaceutical manufacturers are preempted by *Mensing*. *Bartlett v. Mutual Pharmaceutical Co., Inc.*, 678 F.3d 30 (1st Cir. 2012). In *Bartlett*, the plaintiff originally brought claims against Mutual, the generic manufacturer of sulindac, for breach of warranty, fraud, negligence, design defect, manufacturing defect, and failure to warn.

Id. at 34. Prior to trial, all claims with the exception of the design defect claim were dismissed by the district court on summary judgment, or were voluntarily dismissed by the plaintiff. *Id*. The case went to trial under the following theory:

> That sulindac's risks outweighed its benefits making it unreasonably dangerous to consumers, despite the federal Food and Drug Administration ("FDA") having never withdrawn its statutory "safe and effective" designation that the original manufacturer had secured and on which Mutual was entitled to piggyback.

Id.

In discussing the nature of a design defect claim under New Hampshire law, the court found the State's adoption of the theory of liability appearing in Restatement (Second) of Torts §402A to permit the theory pursued by plaintiff:

> Although courts "traditionally have refused to review the reasonableness of the designs of prescription drugs," this court reads New Hampshire law now to permit such review. *Brochu* is consistent with the New Hampshire Supreme Court's adoption of Restatement (Second) of Torts § 402A (1965), which "imposes liability for selling 'any product in a defective condition unreasonably dangerous to the user or consumer' when the product causes injury to the user or consumer."

Id. at 35 (internal citations omitted). The court found that the district court had not erred in allowing the plaintiff "to show that sulindac was in a 'defective condition' by showing that it was "unreasonably dangerous" due to its propensity to cause SJS/TEN." *Id.* at 36.

After noting that the Supreme Court had not yet addressed a generic pharmaceutical manufacturer's liability under a state's tort law for a design defect, the First Circuit discussed the relevant law:

> Because prescription drugs and their warnings are closely regulated by the FDA, Congress might explicitly, or the Supreme Court by implication, have preempted state design defect or inadequate warning claims that allow state juries to second-guess the FDA's seal of approval. But the statute contains no general preemption provision, and in *Wyeth v. Levine*, the Supreme Court rejected implied preemption, saying that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," and that state law serves as a "complementary form of drug regulation."

> Although Wyeth's holding was technically limited to failure-to-warn claims, its logic applies to design defect claims as well. The lower courts agree that the FDCA does not preempt state tort suits against drug manufacturers.
>
> However, in *PLIVA, Inc. v. Mensing*, the Court carved out an exception to Wyeth, finding that the FDCA preempts failure-to-warn claims against generic drug manufacturers. Generic drug manufacturers, unlike brand-name manufacturers, cannot unilaterally change their labels, and thus cannot comply with both federal labeling standards and state law requirements deviating from those standards.

Id. at 37 (citations omitted). The court then addressed the generic defendant's argument that it was not free to alter the molecular composition of its generic drug:

> But although Mutual cannot legally make sulindac in another composition (nor is it apparent how it could alter a one-molecule drug anyway), it certainly can choose not to make the drug at all; and the FDCA might permit states to tell Mutual it ought not be doing so if risk-benefit analysis weights against the drug, despite what the Supreme Court made of similar arguments in the labeling context.
>
> …
>
> On balance, we conclude that the Court adopted a general no-preemption rule in Wyeth and that it is up to the Supreme Court to decide whether PLIVA's exception is to be enlarged to include design defect claims.

Id. at 37-38 (internal citations omitted); *see also Halperin v. Merck, Sharpe & Dohme Corp.,* 11 C 9076, 2012 WL 1204728 (N.D. Ill. Apr. 10, 2012) (finding that *Mensing* did not preempt strict liability design defect claims).

The First Circuit also rejected the contention that plaintiff's design defect claims were preempted merely because they "involved" the generic drug's label:

> Mutual next faults the district court for telling the jury it could "consider the FDA's requirements for drug labels" in determining whether sulindac's warning mitigated its unreasonable dangerousness, and for failing to instruct the jury that Mutual could not legally change sulindac's label. Mutual argues that the jury must have inferred, incorrectly, that it could consider whether Mutual should have improved the warnings. As already explained, under current law the original maker, but not the generic provider, can alter the label.
>
> But the label was relevant to the design defect claim since, although unalterable by Mutual, its arguable inadequacies put limits on the extent to which its dangerousness was offset by adequate warnings; so the lack of a clearer warning made the product itself more dangerous under the risk-benefit test prescribed by *Vautour*.

Id. at 41-42.

As the Court's Order acknowledges, Texas follows the §402A Restatement (Second) of Torts approach to strict products liability. [Doc. 75], pg. 7. The justification for imposing strict liability on a manufacturer absent evidence of negligence is provided in the comments to §402A:

> …the justification for the strict liability has been said to be that the seller, by marketing his product for use and consumption, has undertaken and assumed a special responsibility toward any member of the consuming public who may be injured by it; that the public has the right to and does expect, in the case of products which it needs and for which it is forced to rely upon the seller, that reputable sellers will stand behind their goods; that public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.

Restatement (Second) of Torts §402A, cmt. c.

Thus, Plaintiff's strict liability design defect claim is not "failure to warn" claim, as the Court found, nor does it impose a duty on Generic Defendants to change the content of their drug labeling, such as would be prohibited under *Mensing* or to withdraw their product from the market, as the Court's characterization suggests. Instead, these claims merely require a manufacturer to compensate consumers have been injured by an unreasonably dangerous product. Generic Defendants have not identified any way in which this state law duty conflicts with any provision of federal law, and in fact the interpretation provided by the *Bartlett* Court is entirely consistent with the provisions of Texas law. *See e.g., Borel v. Fibreboard Paper Products Corp.*, 493 F.2d 1076 (5th Cir. 1973).

C. Order Granting Brand Defendants' Motion for Summary Judgment

In Its Memorandum Opinion Granting Brand Defendants' Motion for Summary Judgment, the Court rejected Plaintiffs' argument that the situation at issue in this case was analogous to the one presented to the Texas Supreme Court in *Alm v. Aluminum Co. of America,*

deciding instead that *Firestone Steel Products Company v. Barajas* dictated the proper outcome. [Doc. 79], pg. 5. The Court then determined that all of the claims appearing in Plaintiffs' Second Amended Complaint were product liability claims, rejecting Plaintiffs' assertions that viable non-product liability claims existed against Brand Defendants. *Id.* at pg. 6. The Court then found that the claims asserted against Brand Defendants could not proceed – citing only to the definition of a products liability action. *Id.* at pg. 7; citing Tex. Civ. Prac. & Rem. Code Ann. §82.001(2). argue that Generic Defendants.

1. A Product Liability Claim May Be Asserted Against Brand Defendants

In their complaint, Plaintiffs allege that the Brand Defendants designed Reglan/metoclopramide, and that they crafted the warning labels that would be used not only for their Reglan products, but also for generic metoclopramide. *See* [Doc. 22], ¶¶ 3.02, 3.18, 3.26, 3.40, 3.41. As the Supreme Court made clear in *Mensing*, it is the brand manufacturer alone that has the capability to alter the design of a prescription drug label. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2581 (2011) *reh'g denied*, 132 S. Ct. 55 (U.S. 2011) (stating that a brand manufacturer may strengthen the warning in its label "of its own volition"); *see also Wyeth v. Levine*, 555 U.S. 555, 571 (2009) (noting that prior to 2007, the FDA lacked the authority to order manufacturers to revise their label).

The result is that the Brand Defendants exercised complete control over certain aspects of the design of generic metoclopramide, one of which was the content and design of the label containing the instructions and warnings necessary for safe use of the drug. While Generic Defendants may still be held liable under other theories, there can be no doubt that the generic manufacturer was not free to change the content of its label, except to add warnings that already appeared in the label for Reglan – the ability to include "substantial new warning information" rested solely with the Brand Defendants.

As Plaintiffs argued previously, Texas law provides for liability against an entity that designs, but does not manufacture a product that causes harm, because there is no privity requirement with respect to liability based solely on design. *See* [Doc. 71], pp. 17-20; citing *Alm v. Aluminum Co. of America, Inc.,* 717 S.W.2d 588 (Tex. 1986). The Court's Order found that Brand Defendants could not be held liable under Texas product liability law because Plaintiffs stipulated that these Defendants "did not manufacture, distribute, or sell the metoclopramide ingested by Roy Eckhardt." [Doc. 79], pg. 4. The Court's conclusion ignores, however, the fact that the very statute it relies upon as precluding Plaintiffs' claims provides a much broader definition of "manufacturer" than attributed by the Court. Specifically, §82.001, relied upon by the Court defines a manufacturer as:

> a person who is a designer, formulator, constructor, rebuilder, fabricator, producer, compounder, processor, or assembler of any product or any component part thereof and who places the product or any component part thereof in the stream of commerce.

As Plaintiffs have alleged not only that Brand Defendants designed the label for Reglan/metoclopramide, but also that these were the only defendants who disseminated the information appearing therein, the manufacturers would meet the definition of a "manufacturer" under Texas law. Indeed, courts consistently find that the designer of a product that causes injury may be held liable, despite the fact that the product was manufactured and distributed by another entities. *See e.g., Alm, supra; Jenkins v. Occidental Chemical Corporation,* slip op., --- S.W.3d ---, 2011 WL 6046527 (Ct. App. Tex. 2011); *see also; Iacurci v. Lummus Company,* 340 F.2d 868 (2nd Cir. 1965); *Milford v. Commercial Carriers, Inc.,* 210 F.Supp.2d 987 (N.D. Ill. 2002); *Lawson v. Honeywell Intern., Inc.,* 75 So. 3d 1024, 1026 (Miss. 2011), *reh'g denied* (Dec. 15, 2011); *Vincent v. C.R. Bard, Inc.,* 944 So.2d 1083 (Fla. D.C.A. 2006); *Easter v. Aventis Pasteur, Inc.,* 2004 WL 3104610, *8 (E.D. Tex. 2004); *see also Conte v. Wyeth, Inc.,* 85 Cal. Rptr. 3d 299 (Cal. App. 1st Dist. 2008); *Kellogg v. Wyeth,* 762 F. Supp. 2d 694 (D. Vt. 2010).

Furthermore, as stated above, the Texas Supreme Court recently affirmed *Alm's* applicability in cases involving prescription drugs, calling into doubt this Court's decision to forego the principles announced in that case in favor of those appearing in *Firestone Steel Products Company v. Barajas.* [Doc. 79], pp. 4-5.

2. Plaintiffs' Other Claims Against Brand Defendants Are Not Product Claims

Finally, while certain product-related claims, such as those based on strict liability or breach of implied warranties may require a plaintiff to prove that the injuries complained of were caused by a product manufactured, sold, or supplied by the Defendants, the same cannot be said for all claims appearing in Plaintiffs' Complaint. The Court's finding that the definition appearing in Tex. Civ. Prac. & Rem. Code Ann. § 82.001(2) applies to Plaintiffs' misrepresentation claims ignores a fundamental aspect of that definition. Namely, the statute defines "Products liability action" to mean any action "against a manufacturer or seller" for damages caused by a defective product. *Id.*

If the Court adheres to its finding that Brand Defendants are not "manufacturers" for the purpose of Texas products liability law, then the claims asserted against them would not constitute a "products liability action" as defined by statute. This would make logical sense because Plaintiffs' claims are not based upon the defectiveness of Brand Defendants' products, or the Defendants' status as a manufacturer or seller. Rather, Plaintiffs' claims against Wyeth and Schwarz revolve around the misrepresentations that were made, when it was forseeable that injuries such as those experienced by Plaintiffs were likely to occur. The fact that the injuries were caused by a "product" does not mandate a different result. To find otherwise would mean that every action for damages resulting from a car accident would be a "product liability action" since a vehicle is a "product." Under the Court's ruling, a plaintiff could not sue an individual

whose negligence caused the accident because such action would be considered a "product liability claim" under §82.001, and the plaintiff's sole remedy would be against the manufacturer of the vehicle. Nothing in Texas law supports such a restrictive reading of the products liability statute, and the Court should reconsider its findings in this regard.

III. CONCLUSION

For those reasons appearing above, Plaintiffs respectfully request that the Court reconsider its Order granting Generic Defendants' Motion to Dismiss and its Memorandum Opinion granting Brand Defendants' Motion for Summary Judgment, and that it alter or amend its Judgment in favor of Defendants to reinstate their claims.

Respectfully submitted this 6th day of September 2012,

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically on September 6, 2012, and is available for viewing and downloading from the ECF system. Notice of Electronic Case Filing has been sent automatically to all parties listed in the Service List in effect on the date of electronic filing, which constitutes service of same, and satisfies the requirements of Fed. R. Civ. P. 5(b)(2)(D).

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